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BEFORE THE BOARD OF PATENT APPEALS

AND INTERFERENCES

Paper No. 17

Application Number: 08/487,312

Filing Date: 07 June 1995

Appellant(s): Walter L. MILLER et al.

Kate H. Murashige

For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed 18 June 1997.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 19-22 stand or fall together.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

3,265,579	Daniels et al.	09-1966

(10) New Prior Art

No new prior art has been applied in this examiner's answer.

(11) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 19-22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Daniels et al. (U.S. Pat. No. 3,265,579).

The instant claims encompass bovine growth hormone. Daniels et al. disclose bovine growth hormone which is purified from a tissue source. (See examples 1-6, columns 2-4, especially example 6.) The bovine growth hormone disclosed in the prior art of Daniels et al. appears to be substantially the same as that of the instant claims, wherein such was isolated from bovine tissue, versus the claimed bovine growth hormone that was produced by

recombinant techniques. In the event that the bovine growth hormone of Daniels et al. is not exactly the same as the claimed protein, it is noted that any slight variation in purity or glycosylation would be obvious to one of ordinary skill in the art at the time the invention was made because it is always desirable to obtain proteins in their most pure form and it was well known in the art that proteins could vary in their glycosylation pattern without altering the activity or function of the protein. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent clear and convincing evidence to the contrary.

(12) New Ground of Rejection

This examiner's answer does not contain any new ground of rejection.

(13) Response to argument

Appellants assert that the claimed product, bovine growth hormone, made by recombinant methods, which are recited in the claims, "confers on the claimed product the assurance that it is free of whatever might be the infectious agent in 'Mad Cow Disease'" (at page 3 of the brief). Although this feature was not disclosed in the specification, the argument has been fully considered and addressed in the previous Office Action. Whereas this statement is true in that the recombinant bovine growth hormone would not be expected to contain the infectious agent for bovine spongiform encephalopathy (BSE, also known as Mad Cow Disease), the bovine growth hormone isolated by Daniels et al. also would not be expected to contain BSE and therefore, the instant claims do not distinguish over the prior art of record. Evidence which supports this conclusion is (1) the bovine growth hormone of Daniels et al.

was purified and recovered from centrifugal analysis as a single peak, indicating a pure, homogenous preparation of bovine growth hormone (see column 4, lines 35-38) and (2) the scrapie virus (which is presumed to be the causative agent in BSE) does not co-purify with growth hormone (Science. 228: 1176-1177 at page 1177, column 2, paragraph 2).

Appellants cite *In re Wakefield and Foster*, 164 USPQ 636 (CCPA 1970) for the principal that process limitations will be read into a claim if the limitations are reflected in a mandated characteristic of the product. Appellants admit that they do not rely on the patentability of the recombinant process for patentability of the claimed bovine growth hormone. It should be noted that issue in *In re Wakefield and Foster* involved "synthetic" rubber versus a purified natural product. In the case of rubber, a synthetic product is considered distinct by one of ordinary skill in that art as well as the specification providing support for a distinction between synthetic rubber and rubber purified from a natural source. In the instant application, this distinction between the isolated bovine growth hormone of Daniels et al. and the recombinant bovine growth hormone of the instant claims has not been clearly established and evidence of purity in the Daniels et al. reference is that there was no contamination.

Patentability depends on whether the product is known in the art or obvious, and is not governed by its process of production (In re Klug, 142 USPQ 161); therefore, the burden is upon applicants to establish a patentable difference (In re Fessman, 180 USPQ 324). Further held was that when a prior art product reasonably appears to be the same as the claimed, but differs by process in which it was produced, a rejection of this nature is eminently fair and the burden is upon appellants to prove, by comparative evidence, a patentable difference (In re Brown, 173 USPQ 685; In re Marosi, 218 USPQ 289; In re Thorpe, 227 USPQ 965; In re

Fitzgerald, 205 USPQ 594; and as more recently emphasized in Ex parte Gray, 10 USPQ2d 1922; Amgen Inc. v. Chugai Pharmaceutical Co., 9 USPQ2d 1822; and Scripps Clinic v. Genentech Inc., 3 USPQ2d 1481). Furthermore, in a recent court decision regarding proteins, the decisional law held that recombinantly produced proteins are not patentable or functionally distinct from their native counterpart proteins (Ex parte Gray, 10 USPQ2d 1922; Amgen Inc. v. Chugai, 9 USPQ2d 1833; and Scripps v. Genentech, 3 USPQ2d 1481). In view of the fact that the courts have clearly emphasized that product claims unless there has been established a patentable difference, one having ordinary skill in the art at the time of the invention would have expected that the bovine growth hormone produced by the recombinant process would be functionally/biologically equivalent to native bovine growth hormone as produced by Daniels et al. and would therefore function in a manner taught by the prior art - thus rendering Appellant's claims *prima facie* obvious in the event that the prior art does not anticipate the claims.

Appellants argue that there is a difference between the recombinant bovine growth hormone of the claims and the bovine growth hormone of Daniels et al. However, Appellants state "Appellants **agree** that it is quite unlikely that the actual material exemplified in the Daniels patent contained" the causative agent for BSE (emphasis added). In light of this statement, Appellants have demonstrated a distinction between the bovine growth hormone of Daniels et al. and the product of the instant claims. Appellant also states that the bovine growth hormone of Daniels et al. may not be homogenous. This assertion is unfounded because Daniels et al. demonstrate the isolation and recovery of bovine growth hormone as a single peak after elusion from a Sephadex G-100 column and ultracentrifugal analysis (see column 4, lines 35-38 of Daniels et al.). Appellant further states that "there is absolutely no

guarantee that the Daniels preparation is free" of the causative agent of BSE. However, an absolute guarantee is not the correct standard for determining anticipation or obviousness and a fair reading of the reference is that the bovine growth hormone of Daniels et al. is the same as the bovine growth hormone of the instant claims.

On page 5 of the brief, Appellant address recent FDA regulations and suggest that because FDA regulations will prohibit the use of bovine growth hormone which has been isolated from bovine pituitaries, that the recombinant form of the protein will be required. However, that is not the issue at hand. The issue of the instant rejection is whether the bovine growth hormone of Daniels et al. anticipates or, in the alternative, makes obvious the recombinant bovine growth hormone of the instant claims. Arguments regarding FDA regulations do not appear to bear on this issue.

In the section spanning pages 5 and 6, Appellant addresses two Federal Circuit decisions regarding product-by-process claims. Appellant summarizes by saying that "where a process leads to a product that is different from what appears to be a similar product prepared by a different process ,there would be no doubt that the process limitations would be read into the claims to evaluate infringement". This statement is not contrary to the instant rejection, because it has not been established that the product of the instant application distinguishes over the product of the prior art made by a different method. Appellant has alleged a difference, but the evidence of record supports a conclusion that the bovine growth hormone of Daniels et al. would not contain the causative agent for BSE. The issue of the presence of BSE in preparations of bovine growth hormone does not appear in the instant specification as filed. This argument was first raised by Appellant in response to a first Office action rejection of the claims and several references were cited. As rebuttal for this argument regarding BSE, one of

Appellant's references was used to rebut this argument in that Science (vol. 228, 1985) states that the scrapie virus (which is presumed to be the causative agent in BSE) does not co-purify with growth hormone (see page 1177, column 2, paragraph 2). It is noted that since the disclosure of the instant application contains no mention of BSE, this cannot be included as a claim limitation to distinguish over the prior art. Furthermore, since the Science reference has only been relied upon as rebuttal evidence and not for a claim limitation, it should not be included in the grounds of rejection (see *In re Hoch*, 166 USPQ 406).

Appellant's arguments bridging pages 6-7 are confusing in that it appears that Appellant is asserting that a process-conferred distinction need not be a distinction and that an "absolute guarantee" makes for a patentable distinction. This argument is not found persuasive because even Appellant has conceded that "it is quite unlikely that the actual material exemplified in the Daniels patent contained" the causative agent for BSE (see page 4, final paragraph of brief). Absolute guarantees are not the standard for patentability and the issue at hand is whether the product of Daniels et al. anticipates or makes obvious the product of the claims of the instant application. The bovine growth hormone of Daniels et al. was a homogenous preparation (as demonstrated by a single peak following centrifugal analysis) and the fact that one of ordinary skill in the art would not expect the causative agent for BSE to copurify with bovine growth hormone (see Science reference). Appellant has not rebutted this evidence nor has comparative evidence been submitted to rebut these arguments. Appellant's statement that "even assuming that the Daniels preparation as made is, in fact, free of the BSE causative agent, the important distinction is that it cannot be guaranteed to be so" is not persuasive.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Christine Saoud
August 27, 1997

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